REMARKS

Claims 24, 27-29, 31-34, 36, 40, 81, 82, 91, 94-96, 98-102, 104, 105, 110, and 111 are pending. Claims 81, 82, 104, and 105 have been withdrawn from consideration. Applicants acknowledge with appreciation that the Office has indicated that claims 24, 27-29, 31-34, 36, 91, 94-96, 98-102, 110, and 111 are in condition for allowance. The Office has also listed withdrawn claims 81, 82, 104, and 105 as being in condition for allowance. Applicants respectfully request clarification of the status of claims 81, 82, 104, and 105. Claim 40 is rejected as alleged obvious under 35 U.S.C. § 103(a). Applicants discuss this rejection below.

Rejection Under 35 U.S.C. § 103

Claim 40 remains rejected under 35 U.S.C. § 103(a) as allegedly obvious over Pass *et al.*, *J. Infect. Dis.* 180:970-75 (1999) ("Pass") in view of Cunningham *et al.*, *NEJM* 339:236-44 (1998) ("Cunningham"). Office Action at 3. According to the Office, claim 40 is drawn to a method of treating HIV by administering CMV glycoprotein B to an individual. *Id.* The Office acknowledges that Pass does not teach the treatment of HIV. *Id.* Nonetheless, the Office concludes that "it would have been obvious to apply Pass' method to an HIV patient susceptible to or infected with CMV." *Id.* In addition, the Office finds that "[o]ne of ordinary skill in the art would have been motivated to treat CMV infection in an HIV patient because CMV is an opportunistic pathogen that routinely infects . . . HIV patients. . . . " and notes that Cunningham allegedly "teaches that CMV retinitis affects 30-40% of HIV-positive patients in developed countries." *Id.* at 4. Finally, the Office suggests that one of ordinary skill in the art would have had a

reasonable expectation of success because "Pass' CMV treatment would have worked with HIV patients that are susceptible to infection with CMV." Office Action at 4.

Previously, Applicants explained that in the study described in Pass, humans were injected with a CMV vaccine comprising gB and an adjuvant. *See* Pass at paragraph bridging pages 970 and 971. The purpose of that immunization was to induce immunity in humans against a subsequent infection by CMV. Clearly, Pass does not describe a method of treating a HIV infection in a patient infected with HIV (as the Office agrees), but instead teaches a method of immunizing a patient against future CMV infections. Cunningham does not remedy that deficiency of Pass. Accordingly, Pass and Cunningham together do not render claim 40 obvious.

The Office now responds by suggesting that the administration of gB to HIV infected individuals inherently treats HIV. Office Action at 4. Again, the Office reiterates that it would have been obvious to apply the method of Pass to an HIV infected patient susceptible to CMV infection, relying on the alleged motivation and expectation of success described above. Applicants respectfully traverse.

Applicants respectfully contend that the Office is attempting to rely on an inherency argument, and has not properly done so. As the Court of Appeals for the Federal Circuit has noted

> New uses of old products or processes are indeed patentable subject matter. See 35 U.S.C. § 101 (2000) (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure).

Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1378 (Fed. Cir. 2005). Applying this conclusion to claim 40, even if gB was known, a new use for gB, such as treating HIV infection, is patentable. Indeed, the Court considered a similar rejection in *Perricone* as compared to the inherency-based rejection the Office makes against claim 40.

In *Perricone*, claim 1, a claim to a method for treating skin sunburn comprising topically applying to the skin sunburn a known fatty acid ester of ascorbic acid to solubilize in the skin an amount effective to scavenge free radicals present as a result of UV radiation of the skin was rejected. *Id.* The district court incorrectly determined that this claim was anticipated by a reference (Pereira) that taught a cosmetic composition for topical application and disclosed various ingredients of the composition, among them a fatty acid ester of ascorbic acid. *Id.* at 1376. The reference further disclosed 8 distinct compositions with specific concentrations of each ingredient and the reference characterized these compositions briefly as suitable for topical application to the skin or hair. *Id.*

Based upon these teachings, the district court concluded that the reference anticipated this claim because the reference's disclosed compositions contained all the ingredients in the concentrations recited in the rejected claim and thus, according to the district court, the topical application of the reference's disclosed compositions would necessarily or inherently yield the claimed skin benefits. *Id.*

The Federal Circuit, however, reversed the district court's finding of anticipation. The Court noted that

> the issue is not whether Pereira's lotion if applied to the skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn.

Perricone at 1378 (emphasis added). The Court noted that the reference's use of topical application did not suggest application for treatment of sunburn. *Id.* at 1379. The reference was silent about any sunburn prevention, treatment benefits, or the mechanisms underlying such uses. *Id.* The Court concluded that the district court assumed what the reference neither disclosed nor rendered inherent. *Id.*

Applicants contend that the Office uses the same erroneous logic to reject claim 40 as the district court employed in *Perricone*. Specifically, the Office contends that because Pass administers gB to its subjects, the administration of gB would inherently treat HIV infection in those subjects, *if* HIV were present.

Appellants note that the Federal Circuit did find independent claim 8 and its dependent claims inherently anticipated. Unlike claim 1, however, which described a new method of using a known compound, claim 8 described a known method of using a known compound because claim 8 merely required application of a composition to exposed skin. *See Perricone* at 1379. The reference used against these claims taught that the composition could be applied topically. The Court found that the reference's teaching of topical application satisfied the claim element of applying the composition to exposed skin because all skin surfaces are susceptible to sunburn damage and the only type of skin one would apply a compound to would be exposed skin. *See id.* Thus, the Court concluded, the concept of topical application as applied to rejected claim 8 would cover application to skin susceptible to sunburn and to exposed skin.

Applying the appropriate rationale articulated by the Federal Circuit in *Perricone* to the Office's rejection of claim 40, the issue is not whether Pass' CMV vaccine comprising gB if administered to a human would inherently treat an HIV infection, but

whether Pass discloses the application of its gB composition to treat HIV infection. Clearly, Pass does not teach a method of treating an HIV infection of a human comprising "administering to the human a molecule . . . wherein the molecule . . . comprises a binding moiety of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor." The Office admits that "Pass does not teach the treatment of HIV." Office Action at 3. Thus, Pass neither explicitly nor inherently teaches the method of claim 40.

Cunningham's alleged teaching that CMV retinitis affects 30-40% of HIV-positive patients in developed countries does not compensate for the inadequacy of Pass' disclosure. Even if the Office's summary of Cunningham's teaching were true, it does not suggest that all humans that suffer from a CMV infection are also infected with HIV. Thus, by analogy to the Federal Circuit's analysis of claims 8, 9, and 13 in *Perricone*, where the Court concluded that all skin surfaces were susceptible to sunburn damage, not all individuals infected with CMV are also infected with HIV. Applicants have explained that Pass does not teach administering their vaccine to CMV infected individuals. Rather, the patients who received the gB injection were not at that time infected with CMV. (*See* Pass at page 970, "Study population and enrollment criteria.") Indeed, Pass selects out those individuals who are immunocompromised or who have sexually transmitted diseases, for example, individuals with an HIV infection. *See id.* *Arguendo*, even if Pass taught the treatment of CMV infected individuals, this still would not inherently teach the treatment of HIV infected individuals because not all CMV infected individuals are also infected with HIV.

In sum, the Office's reasoning that the administration of gB to HIV infected individuals inherently treats HIV runs afoul of the current case law. There is nothing in Pass to suggest that the subjects were HIV positive. Just because Pass may seek to prevent CMV infection via its vaccine, this is not an inherent teaching of treating HIV infections. Thus, claim 40 is not obvious over Pass in view of Cunningham. Applicants respectfully request that the Office withdraw this rejection.

Conclusions

Applicants respectfully request that this Reply under 37 C.F.R. § 1.116 be entered by the Office, placing claim 40 in condition for allowance. Because Applicants have not amended the claims, this Reply should allow for immediate action by the Office.

Furthermore, Applicants respectfully point out that the final action by the Office presented a new argument as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of the Reply would allow the Applicant to respond to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the Reply would place the application in better form for appeal, should the Office dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention is not rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Reply, the Examiner's reconsideration and reexamination of the application, and the timely allowance of claims 24, 27-29, 31-34, 36, 40, 81, 82, 91, 94-96, 98-102, 104, 105, 110, and 111.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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